

THE CLAIMS

What is claimed is:

1. A self-blunting needle cannula device comprising:

(a) an external component comprising a needle cannula having an outside diameter, a through-bore having a through-bore diameter, a tip comprising a puncture tip, a mounting end, and an external component hub on the needle cannula spaced from the tip;

(b) an internal component comprising an elongate blunting member having a tip defining a blunt tip, and an internal component hub on the blunting member and spaced from the tip, the blunting member being disposed within the through-bore of the needle cannula;

wherein the external component and the internal component are movable relative to each other between a sharpened configuration in which the blunt tip is positioned short of the puncture tip of the needle cannula to leave the puncture tip exposed, and a blunting configuration in which the blunt tip extends beyond the puncture tip of the needle cannula to effectively blunt the device; and

(c) a guide surface on the device that leads axially towards the through-bore so that the guide surface can serve as a guide for the insertion of the blunting member into the through-bore during assembly of the device.

2. The device of claim 1 wherein the guide surface converges axially from a first entry aperture larger than the through-bore to a first gate aperture not larger than the through-bore, the first gate aperture being aligned with the through-bore.

3. The device of claim 1 wherein the guide surface comprises a non-convergent surface that defines a groove that is positioned and configured to guide the blunting member into the through-bore of the needle cannula.

4. The device of claim 3 wherein the guide surface further comprises a portion that converges axially from a first entry aperture larger than the through-bore to a first gate aperture not larger than the through-bore, the first gate aperture being aligned with the through-bore.

5. The device of claim 3 or claim 4 wherein the first entry aperture has a diameter in the range of from about 0.5 to 0.009 inch and the first gate aperture has a diameter in the range of from about 0.203 to 0.006 inch.

6. The device of claim 2 or claim 4 wherein the needle cannula defines a longitudinal axis and wherein at least a portion of the guide surface defines an angle  $\alpha$  relative to the needle cannula axis and wherein the angle has a magnitude in the range of from about 5 to 75 degrees.

7. The device of claim 2, claim 3 or claim 4 comprising a guide member disposed at the mounting end of the needle cannula, the guide member defining the guide surface.

8. The device of claim 7 wherein the guide member is disposed within the external component hub.

9. The device of claim 7 wherein the guide member is integrally formed as part of the external component hub.

10. The device of claim 9 wherein the guide member comprises an alignment lug formed on the external component hub.

11. The device of claim 3 comprising a guide member having a first end at which the first guide surface is formed and an opposite, second end at which is formed a second entry aperture larger than the needle cannula and a second guide surface that converges axially to a second gate aperture smaller than the second entry aperture but not smaller than the needle cannula, the guide member further comprising a

passage extending between and axially aligned with the first and second gate apertures, the needle cannula extending through the second gate aperture and the mounting end of the needle cannula being mounted within the passage, and wherein the second guide surface converges from the second entry aperture towards the bore to the second gate aperture, to serve as a guide for the insertion of the mounting end of the needle cannula into the passage during assembly of the device.

12. The device of claim 11 wherein the first gate aperture is smaller than the passage in the guide member and smaller than the needle cannula so that the guide member defines in the passage a stop shoulder at the first gate aperture. 1A

13. The device of claim 11 wherein the second entry aperture has a diameter in the range of from about 0.5 to 0.009 inch and the second gate aperture has a diameter in the range of from about 0.203 to 0.006 inch.

14. The device of claim 11 wherein the second guide surface defines an angle  $\alpha$  relative to the needle cannula axis and wherein the angle has a magnitude in the range of from about 5 to 75 degrees.

15. The device of any one of claims ~~1 through 5~~ <sup>1-4</sup> in combination with a syringe comprising an actuation member for moving the device from a sharpened configuration to a blunted configuration.

16. A self-blunting needle cannula device comprising:

(a) an external component comprising a blunting member having an outside diameter, a through-bore having a through-bore inside diameter, an outward end comprising a blunt tip, a mounting end, and an external component hub on the blunting member and spaced from the tip;

(b) an internal component comprising an elongate needle cannula having an outward end comprising a puncture tip, and an internal component hub on the needle cannula and spaced from the puncture tip, the needle cannula being disposed within the through-bore of the blunting member of the external component;

29. The device of claim 27 wherein the second guide surface defines an angle *a* relative to the needle cannula axis and wherein the angle has a magnitude in the range of from about 5 to 75 degrees.

30. The device of claim 17 or claim 18 in combination with an actuation member for moving at least one of the blunting member and the needle cannula relative to each other to change the device from its sharpened configuration to its blunted configuration.

31. In a method for assembling a device comprising inserting an internal component within an external component having an axially-extending through-bore therein dimensioned and configured to receive the internal component, the improvement comprising advancing the internal component into contact with a guide surface configured to lead axially to the through-bore to guide the internal component into the bore to produce an assembled device.

32. The method of claim 31 comprising advancing the internal component into contact with a non-convergent guide surface.

33. The method of claim 31 comprising advancing the internal component into contact with an axially convergent guide surface.

34. The method of claim 33 wherein the guide surface defines an entry aperture that is larger than the through-bore of the external component and converges to a gate aperture that is not larger than the through-bore of the external component, the gate aperture facing and being aligned with the through-bore, the method comprising aligning the internal component with the entry aperture and advancing the internal component towards the external component so that the internal component passes through the entry aperture, into contact with the guide surface and then through the exit aperture and into the bore.

21 35. The method of claim 17, claim 18 or claim 19 comprising contacting the external component with a first guide surface and contacting the internal component with a second guide surface.

22 36. The method of claims 17, 18, 19, 20 wherein the guide surface is provided by a non-integral guide member and wherein the method comprises removing the assembled device from the guide member.

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37. The method of claim 36 wherein the external component comprises a cannula having a tip and a mounting end mounted in a hub, the hub defining an aperture that permits access to the through-bore by the internal component, wherein the guide member comprises a funnel having a gate aperture and an exit aperture and wherein the method comprises aligning the gate aperture of the funnel with the through-bore at the tip of the cannula, passing the internal component through the guide member and removing the assembled device from the guide member.

24 38. The method of claim 23 further comprising securing a nut to the internal component after the internal component passes through the guide member.

39. A method for assembling a self-blunting needle device comprised of (i) an external component comprising a needle cannula having an outside diameter, a through-bore having a through-bore diameter, a puncture tip and a mounting end; and (ii) an internal component comprising an elongate blunting member having an outside diameter and a blunt tip, and, after assembly, being disposed within the through-bore of the needle cannula;

the method comprising the steps of:

(a) positioning a guide member having a guide surface relative to the external component so that the guide surface leads axially to the through-bore; and

~~(b) advancing the blunting member into contact with the guide surface to guide the blunting member into the through-bore of the needle cannula.~~

40. The method of claim 39 comprising disposing the needle cannula on a first guide surface and advancing the blunting member into contact with a second guide surface.

543 26 41. The method of claim 39 comprising providing a guide member having a first end and a second end and a passage that extends axially from the first end to the second end and further comprising at the first end a first guide surface that leads axially to the passage and at the second end a second guide surface that leads axially to the passage, wherein the passage is sized to receive the needle cannula, the method further comprising, before steps (a) and (b), disposing the needle cannula with its mounting end disposed towards and in alignment with the second guide surface and advancing the needle cannula into contact with the second guide surface and into the passage and into alignment with the first gate aperture.

28 26 42. The method of claim 39 or claim 41 further comprising the steps of installing the self-blunting needle device in a medical fluid-handling device comprising an actuation member for moving the device between the sharpened configuration and the blunted configuration.

43. A method for assembling a self-blunting needle device comprised of (i) an external component comprising a blunting member having an outside diameter, a through-bore having a bore inside diameter, an outward end comprising a blunt tip and a mounting end; and (ii) an internal component comprising an elongate needle cannula having an outside diameter and an outward end comprising a puncture tip, and, after assembly, being disposed within the through-bore of the cannula member of the external component;

the method comprising the steps of:

(a) positioning a guide member having a guide surface relative to the external component so that the guide surface leads axially to the through-bore; and

(b) advancing the needle cannula into contact with the guide surface to guide the needle cannula through the first entry gate thence into the through-bore of the blunting member.

wherein the external component and the internal component are movable relative to each other between a sharpened configuration in which the blunt tip is positioned short of the puncture tip of the needle to leave the puncture tip exposed and a blunted configuration in which the blunt tip extends beyond the puncture tip of the needle to effectively blunt the device; and

(c) a guide member at the mounting end of the blunting member defining a first guide surface that leads axially towards the through-bore to serve as a guide for the insertion of the needle cannula into the through-bore during assembly of the needle cannula device.

17. The device of claim 16 wherein the guide surface converges axially from a first entry aperture larger than the through-bore to a first gate aperture not larger than the through-bore, the first gate aperture being aligned with the through-bore.

18. The device of claim 16 wherein the guide surface comprises a non-convergent surface that defines a groove that is positioned and configured to guide the blunting member into the through-bore of the needle cannula.

19. The device of claim 18 wherein the guide surface further comprises a portion that converges axially from a first entry aperture larger than the through-bore to a first gate aperture not larger than the through-bore, the first gate aperture being aligned with the through-bore.

20. The device of claim 17 or claim 19 wherein the first entry aperture has a diameter in the range of from about 0.5 to 0.009 inch and the first gate aperture has a diameter in the range of from about 0.203 to 0.006 inch.

21. The device of claim 17 or claim 19 wherein the needle cannula defines a longitudinal axis and wherein at least a portion of the guide surface defines an angle  $\alpha$  relative to the needle cannula axis and wherein the angle has a magnitude in the range of from about 5 to 75 degrees.

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22. The device of claim 17 or claim 19 wherein the first gate aperture is smaller than the passage to define in the passage a stop shoulder at the first gate aperture.

23. The device of claim 17, claim 18 or claim 19 comprising a guide member disposed at the mounting end of the blunting member, wherein the guide member defines the guide surface.

24. The device of claim 23 wherein the guide member is disposed within the external component hub.

25. The device of claim 23 wherein the guide member is integrally formed as part of the external component hub.

26. The device of claim 25 wherein the guide member comprises an alignment lug formed on the external component hub.

27. The device of claim 16 wherein the guide member has a first end at which the first guide surface is formed and an opposite, second end at which is formed a second guide surface, a second entry aperture larger than the blunting member and a second gate aperture smaller than the second entry aperture but not smaller than the blunting member, the guide member further comprising a passage extending between and axially aligned with the first and second gate apertures, the blunting member extending through the second gate aperture and the mounting end of the blunting member being mounted within the passage, and wherein the second guide surface converges from the second entry aperture to the second gate aperture, to thereby serve as a guide for insertion of the mounting end of the blunting member into the passage during assembly of the device.

28. The device of claim 27 wherein the second entry aperture has a diameter in the range of from about 0.5 to 0.009 inch and the first gate aperture has a diameter in the range of from about 0.203 to 0.006 inch.

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45. The method of claim 43 comprising providing a guide member having a first end and a second end and a passage that extends axially from the first end to the second end and further comprising at the first end a first guide surface that leads axially to the passage and at the second end a second guide surface that leads axially to the passage, wherein the passage is sized to receive the needle cannula,

46. The method of claim 43, claim 44 or claim 45 further comprising the steps of installing the self-blunting needle device in a medical fluid-handling device comprising an actuation member for moving the blunting member and the needle cannula relative to each other to change the blunting member from its retracted position to its extended position.

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